K093382

SCOTTCARE

ScottCare Corporation
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AUG 18 2009

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is _____.

Date:	November 12, 2008
Submitted by:	ScottCare Corporation Registration No: 1527715 4791 West 150th Street Cleveland, OH 44135
Contact Person:	Mr. Timothy J. Leyva 216-362-0550 # 113 216-264-6129 Fax tleyva@scottcare.com
Manufacturing Site:	ScottCare Corporation Registration No: 1063268 4897 W. Waters Ave, Suite J Tampa, Florida 33634
Trade Name:	Chroma
Common Name:	Digital Holter Recorder
Classification:	870.2800 Medical Magnetic Tape Recorder
Product Code:	DSH
Legally Marketed Predicate Device(s):	DXP1000 Holter Recorder K993618, November 24, 1999

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Device Description:

The basic operation of the Chroma Holter Recorder RZ153C is to collect and store multiple channels of ECG data. The Holter scanner software reads this data and it can be printed out in tabular form or graphical form.

This recorder is not capable of any diagnosis nor can it provide any interpretation of the data. It can only display and store the data. The Holter for Windows software reads this data and provides ability to the user to review, edit and print the data collected.

Indications for Use:

The intended use of the Chroma Holter Recorder RZ153C is to perform ambulatory ECG on the order of a physician, on those patients who may benefit from such a recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality such as patients who have recently received pacemakers. The data obtained at recording is not analyzed at the time of the recording.

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Substantial Equivalence:

Features	ScottCare Chroma	Predicate Device DXP1000 Holter Recorder
510(k) Number	TBD	K993618
Date Cleared	TBD	November 24, 1999
Number of ECG Channels	3	2 or 3
Sample Rate & Resolution	128-1024Hz / 8,10 or 12 bit	128-1024Hz / 8 or 10 bit
Input Voltage Range	+/- 5mV	+/- 5mV
Analog Bandwidth	0.05 to 40 Hz	0.05 to 60 Hz
Pacemaker Detection & Reporting	Yes	Yes
Open-Lead Detection & Reporting	Yes	Yes
Recording Time	Unlimited, based on memory capacity	Up to 72 hours
Memory Type	Removable flash memory (SD card)	Removable flash memory (CF card)
Memory Capacity	Up to 2.0GB	Up to 2.0GB
Data Transfer Method	Removable memory card or USB	Removable memory card
Memory Card Data Format	Standard FAT format	Standard FAT format
Display	262k color OLED	Monochrome LCD
Keypad	Protected membrane switch keys	Protected membrane switch keys
Number of keys	5	5
Battery	1 – 1.5V AAA	1 – 1.5V AA

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Features	ScottCare Chroma	Predicate Device DXP1000 Holter Recorder
Battery Check Prior to Recording	Yes	Yes
Internal Clock with Battery	Yes	Yes
Clock Setting Functionality	Yes	Yes
External Patient Cable	Yes	Yes
Record identification procedure	Yes	Yes
ECG channel preview	Yes	Yes
Signal quality check prior recording	Yes	Yes
Multi-language support	Yes	Yes
Autostart when ready	Yes	Yes

Testing Results Summary:

Appropriate testing was conducted in accordance with established design control procedures. The Chroma Holter recorder RZ153C was tested alongside the DXP1000 Holter recorder in a number of situations, including simulated normal ECG signals, simulated paced ECG signals, and on-person ECG signals in laboratory tests. Data recorded by both devices were loaded analyzed in the Holter for Windows scanner software. In all tests, the Chroma Holter recorder produced results very similar to the DXP1000 Holter recorder.

Conclusion:

The Chroma Holter recorder RZ153C and the DXP1000 Holter recorder are both used in clinical applications to collect ambulatory electrocardiographic recordings that can be downloaded to the Holter for Windows® scanner software.

The RZ153C conforms to Good Manufacturing Procedures outlined by the FDA cGMP. This recorder is safe and effective for the application for which it is intended and has been tested to confirm the safety and efficacy of the recorder. The RZ153C is found to be **substantially equivalent** to the DXP1000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Mr. David Norberg
Regulatory Affairs Representative
Braemar, Inc.
11481 Rupp Drive
Burnsville, Minnesota 55337

Re: K993618
DXP1000 Holter Recorder
Regulatory Class: II (two)
Product Code: MWJ
Dated: October 25, 1999
Received: October 26, 1999

Dear Mr. Norberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DXP1000 Holter Recorder

510(k) Number: K99 3618

Indications for Use:

(No change from predicate device)

The electrocardiogram (ECG) is a graphic description of the electrical activity of the heart. This activity is recorded from the body surface by a group of electrodes positioned at predefined places to reflect the activity from different perspectives. Depending on how these electrodes are placed, the ECG waveforms are considered as separate linearly dependent signals. Presently, the ECG is the most prominent and widely used non-invasive cardiac diagnostic technique. There exists a significant accumulation of correlated clinical data which provides a powerful basis for evaluation of these biophysical signals. Twenty-four or forty-eight hour ECG recordings can be of great value in patient assessment.

Ambulatory (Holter) ECG intended use:

The DigiTrakPlus Holter recorder is intended for patients requiring ambulatory (Holter) monitoring from 1 to 48 hours. Such monitoring is most frequently used for the indications below.

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
3. Evaluation of patients for ST segment changes.
4. Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
5. Clinical and epidemiological research studies.
6. Evaluation of patients with pacemakers
7. Reporting of time and frequency domain heart rate variability
8. Reporting of QT Interval

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993618

Prescription Use X
(Per 21 CFR 801.109)

NOV 24 1999

K993618

Section 2: 510(k) SUMMARY

- **Substantially Equivalent (SE) To:** Biosensor Model #1005
  510(k) # K950944

Modification Background

The essence of this modification is a change of the digital Holter recorder hardware to a smaller configuration with reduced power consumption and the removal of ECG analysis capabilities from the device. In connection with this modification, the methodology of the pacemaker detection logic has been modified slightly, and its performance validated as reported herein. As a result of this modification, ECG analysis is not a part of this device, but rather is performed by software installed in the Holter Analyzer which is subject to independent 510(k) review, as in the Company's earlier filing (K990956).

The above changes do not affect the intended use of the device or alter the fundamental scientific technology of the device, as is demonstrated on the following pages.

- **Comparison To The SE Device:**

Attribute	DXP1000	Model #1005
Storage capacity	Up to 48 hours	24 hours
Memory type	Flash (non-volatile)	Flash (non-volatile)
Memory portability	Non-removable	Non-removable
On-board ECG analysis	No	Yes
Liquid Crystal Display (LCD)	Yes	No
Data transfer method	USB port	Bi-directional parallel I/O
Pacemaker detection & reporting	Yes	Yes
Belt clip	Yes	No
Battery	One AA	Four AA
Size	11 x 7 x 2cm	15 x 6 x 2 cm
Weight	135g	140 g

NOTE: Together with this Special 510(k), another Special 510(k) has been filed on a similar device (DigiTrakPlus) utilizing alternative hardware which is slightly smaller in size. Both devices incorporate the same fundamental scientific technology, and indeed a substantially identical electro-mechanical design. For clarity, the submitter wishes to note to the reviewer that these two devices are essentially the same other than the size and weight characteristics noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 13 2009

ScottCare Corporation
c/o Mr. Timothy J. Leyva
Regulatory/Quality Manager
4791 West 150th Street
Cleveland, OH 44135

Re: K083382
Trade/Device Name: Chroma Holter Recorder RZ153C
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (Two)
Product Code: MWJ
Dated: August 3, 2009
Received: August 5, 2009

Dear Mr. Leyva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ScottCare Chroma (RZ153C)

Indications for Use:

The intended use of the Chroma Holter Recorder RZ153C is to perform ambulatory ECG on the order of a physician, on those patients who may benefit from such a recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality such as patients who have recently received pacemakers. The data obtained at recording is not analyzed at the time of the recording.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083382